

REMARKS

Claims 27 to 52 are pending in the current application. No new claims are added. The Examiner is thanked for indicating that claims 46, 47 and 52 comprise allowable subject matter. It is respectfully submitted that the following remarks present no new issues or new matter and place this case in condition for allowance. Reconsideration of the application in view of the following remarks is respectfully requested.

I. Rejection of Claims 27-45 and 48-51 under 35 U.S.C. § 103(a)

Claims 27-45 and 48-51 were rejected under 35 U.S.C. § 103 as being unpatentable over W097/22340 (the WO '340 application) in view of Giger et al., US 5,510,353 (the '353 patent). According to the Office Action, the WO '340 application discloses a tablet composition comprising tolfenamic acid, alginic acid and at least 6% by weight of a superdisintegrant, and that although the WO '340 application does not disclose a tablet composition containing an acid sensitive agent, that it would have been obvious to one skilled in the art to modify the tablet composition of the WO '340 application to include the serotogeneric compound(s) as disclosed in the '353 patent. Applicants respectfully traverse this rejection because the WO '340 application, either alone or in view of the '353 patent, does not disclose or suggest the claim invention as alleged in this rejection.

The WO '340 application discloses a rapid-release formulation of tolfenamic acid. This rapid release is achieved through the use of a superdisintegrant and by using particles with a mean particle size of ≤ 10 microns. (WO '340, page 3, lines 7-14.) Therefore, the rapid-release properties are derived from the fact that the tablets contain smaller particles which will dissolve more quickly and through the use of superdisintegrants causing the tablet to disintegrate rapidly. The WO '340 application also discloses that tolfenamic acid is useful for the treatment of patients suffering from rheumatic diseases and that tolfenamic acid products are marketed for use as anti-inflammatory, analgesic agents, and anti-migraine agents. (WO '340, page 1, lines 11 -24.) There is not indication anywhere in the WO '340 application that tolfenamic acid is an acid sensitive agent. Accordingly, the WO '340 application does not disclose or suggest each and every element of the currently pending claims.

The motivation or suggestion to combine references in the manner suggested in the Office Action must come from the references. There is no disclosure, direction or motivation in either reference to suggest the combination asserted in the Office Action. There would be no motivation for one skilled in the art to combine the WO '340 application with the '353 patents as suggested in the Office Action. The '353 patent is directed to aminoguanidine compounds and their use in treating patients with gastrointestinal motility disorder or disorders associated with

cephalic pain. There is no motivation for one skilled in the pharmaceutical formulation arts trying to overcome the issues associated with the use of acid sensitive drugs, as claimed in the present applications, to turn to the WO '340 application which is directed to the formulation of a rapidly-disintegrating tablets and which is not directed to overcoming the problems associated with acid sensitivity. Further, there is no indication in the WO '340 application that tolfenamic acid - which is disclosed for use in the treatment of rheumatic diseases or as anti-inflammatory and anti-migraine agents - would be useful as an agent for the treatment of gastrointestinal motility disorders or disorders associated with cephalic pain. Accordingly, there is no motivation or suggestion in either of the cited references to combine them in the manner suggested in the Office Action to produce the presently claimed invention.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection of claim 27-45 and 48-51.

In view of the above, it is respectfully submitted that all of the claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

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Respectfully submitted,



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